



JKW

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Alexander HILLISCH et al.

Serial No.: 10/631,967

Group Art Unit: 1614

Filed: 1 August 2003

Examiner: Unknown

For: PROGESTRONE RECEPTOR MODULATORS WITH INCREASED ANTIGONADOTROPIC ACTIVITY FOR FEMALE BIRTH CONTROL AND HORMONE REPLACEMENT THERAPY

INFORMATION DISCLOSURE STATEMENT UNDER 37 CFR §§ 1.56, 1.97 and 1.98

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

This information disclosure statement is made in accordance with 37 C.F.R. §§ 1.56, 1.97 and 1.98 as follows:

Timing and Fees

- ☒ Under 37 C.F.R. § 1.97(b), no fee or statement is required for filing this information disclosure statement is filed:
- ☐ within three months of the filing date of a national application other than a CPA under § 1.53(d);
 - ☐ within three months of the actual filing date of the national phase of a PCT application; OR
 - ☒ before the mailing of a first substantive office action (including after filing of an RCE).
- ☐ Under 37 C.F.R. § 1.97(c), this information disclosure statement is filed after the periods specified in 37 C.F.R. § 1.97(b), but before the mailing date of:
- a final rejection under 37 C.F.R. 1.113;
 - termination of prosecution, e.g. Ex Parte Quayle, M.P.E.P § 609(B)(2); OR
 - a notice of allowance under 37 C.F.R. § 1.311; and

is accompanied by:

- ☐ the statement as specified in 37 C.F.R. § 1.97(e) set out below; OR
- ☐ a check covering the fee of \$180.00 under 37 C.F.R. § 1.17(p).

☐ Under 37 C.F.R. § 1.97(d), this information disclosure statement is filed after the mailing date of the following actions which have not been withdrawn:

- ☐ a final action under 37 C.F.R. § 1.113;
- ☐ termination of prosecution, e.g. Ex Parte Quayle, M.P.E.P § 609(B)(2);
- ☐ OR a notice of allowance under 37 C.F.R. § 1.311;

AND is filed on or before payment of the issue fee; AND is accompanied by:

the statement as specified in 37 C.F.R. § 1.97(e) as set forth below, and the fee of \$180.00 under 37 C.F.R. § 1.17(p).

Statements Under 37 C.F.R. 1.97(e)

- ☐ Each item of information contained in this information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application having a mailing date not more than three months prior to the filing date of this information disclosure statement; or
- ☐ No item of information contained in this information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and to the knowledge of the undersigned attorney after making reasonable inquiry, no item of information contained in this information disclosure statement was known to any individual designated in 37 C.F.R. § 1.56(c) more than three months prior to the filing date of the information disclosure statement.

Cited Materials

- ☐ Copies of materials listed but not attached were cited in benefit (35 U.S.C. § 120) ancestor application Serial No. _____, on Form 892 by the Examiner and/or Form 1449 by the applicant; see 37 C.F.R. § 1.98(d).
- ☐ Copies of materials listed but not attached were cited in an international search report dated _____.
- ☐ Not required by 37 CFR § 1.98.

- ☒ Copies of the materials listed are attached (except for the foregoing).

Non-English Language References

- ☐ An English-language search report or equivalent paper from a foreign patent office is provided indicating the relevance of the cited reference(s).
- ☐ A foreign-language search report from a foreign patent office is provided, and pertinent parts are translated substantively below:

X = document of particular relevance when it is taken alone
Y = document of particular relevance when it is combined with another such document
A = document defining the general state of the art
O = non-written disclosure
P = intercalated document
T = document cited to understand the theory or principle underlying the invention
E = patent document which has the benefit of a date earlier than the filing date and which was published only on or after this filing date
D = cited in the application
L = cited for another reason
& = publication of member of same patent family

- ☐ Translation of other relevant information on foreign search report

[insert necessary translation here]

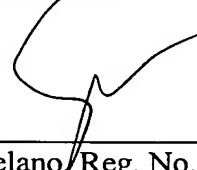
Other Information

Payment of Fees Due (If Any):

- ☐ A check for \$_____ covering the fee identified above is attached.
- ☐ Please charge to Deposit Account No. 13-3402 \$_____ for the fee identified above.

☒ The Commissioner is hereby authorized to charge or credit any overpayment to Deposit Account #13-3402, two copies of this paper are attached for this purpose.

Respectfully submitted,



Anthony J. Zelano, Reg. No. 27,969
Attorney for Applicants

MILLEN, WHITE, ZELANO
& BRANIGAN, P.C.
Arlington Courthouse Plaza 1
2200 Clarendon Blvd. Suite 1400
Arlington, Virginia 22201
Telephone: (703) 243-6333
Facsimile: (703) 243-6410

Attorney Docket No.: GULDE-0002

Date: June 22, 2005

AJZ:at

K:\GULDE2\Information Disclosure Statement.doc



JUN 22 2005

Please type a plus sign (+) inside this box

PTO/SB/08A (08-00)

Approved for use through 10/31/2002. OMB 0651-0031

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449A/PTO

(use as many sheets as necessary)

Sheet	1	of	2
-------	---	----	---

Complete if Known

Application Number	10/631,967
Filing Date	1 August 2003
First Named Inventor	Alexander HILLISCH et al.
Group Art Unit	1614
Examiner Name	Unknown
Attorney Docket Number	GULDE-0002

U.S. PATENT DOCUMENTS

[illegible]

FOREIGN PATENT DOCUMENTS

[illegible]

Examiner
Signature

Date
Considered

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Unique citation designation number. ² See attached Kinds of U.S. Patent Documents. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached. Number refers to English language corresponding family member.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231. **DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO:** Commissioner of Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Please type a plus sign (+) inside this box → +

PTO/SB/08A (08-00)

Approved for use through 10/31/2002. OMB 0651-0031
U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number

Substitute for form 1449A/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

Sheet 2 of 2

Complete if Known

Application Number	10/631,967
Filing Date	1 August 2003
First Named Inventor	Alexander HILLISCH et al.
Group Art Unit	1614
Examiner Name	Unknown
Attorney Docket Number	GULDE-0002

NON PATENT LITERATURE DOCUMENTS

Examiner Initials *	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
	5	D. LOUTRADIS ET AL., "Preovulatory effects of the progesterone antagonist mifepristone (RU486) in mice," Human Reproduction, 1991, vol. 6, no.9, pages 1238-1240.	
	6	K. CHWALISZ ET AL., "Antiproliferative effects of progesterone antagonists and progesterone receptor modulators on the endometrium," Steroids, 2000, vol. 65, pages 741-751.	
	7	O.D. SLAYDEN ET AL., "Reversible suppression of menstruation with progesterone antagonists in rhesus macaques," Human Reproduction, 2001, vol. 16, no. 8, pages 1562-1574.	
	8	W. ELGER ET AL., "Endocrine pharmacological characterization of progesterone antagonists and progesterone receptor modulators with respect to PR-agonistic and antagonistic activity," Steroids, 2000, vol. 65, pages 713-723.	
	9	W. ELGER ET AL., "Sulfamates of various estrogens are prodrugs with increased systemic and reduced hepatic estrogenicity at oral application," J. Steroid Biochem. Molec. Biol., 1995, vol. 55, no. 3/4, pages 395-403.	
	10	E. M. COUTINHO ET AL., "Is Menstruation Obsolete?" 1999, New York, Oxford University Press.	
	11	E.ISAKSSON ET AL., "Effects of oral contraceptives on breast epithelial proliferation," Breast Cancer Research and Treatment, 2001, vol. 65, pages 163-169.	
	12	A. J. SPIEGEL ET AL., "Use of nonaqueous solvents in parenteral products," Journal of Pharmaceutical Sciences, October 1963. vol. 52, no.10, pages 917-927.	
	13	Von Professor Dr. H. v. Czetsch-Lindenwald, "Pentaerythritester als pharmazeutische Hilfsstoffe," Pharmazeutische Technologie, 1961, Jahrg. 23, p. 72-74.	
	14	Arzneimittel, Synthetische s. Chemotherapie und Pharmakotherapeutica, Arzneimittelzubereitung, pages 1-40	
	15	LOUIS J. RAVIN, "Preformulation," Bioavailability and Bioequivalency Testing, Chapter 75, pages 1355-1497	
	16	DWIGHT L. DEARDORFF, "Ophtalmic Preparations," Medicated Applications, Chapter 86, pages 1498-1628.	
	17	ROUSSEL-UCLAF, "Nouveau medicament notmment pour le traitement des troubles dus a une insuffisance de secretion de corps jaune," Bulletin officiel de la Propriete industrielle, no. 30 du 24 juillet 1967.	
	18	G. TEUTSCH ET AL., "11Beta-substituted steroids, an original pathway to antihormones, 1988, vol. 31, no. 4B, pages 549-565.	
	19	XIANG-SHU FEI ET AL., "New, convenient route four trifluoromethylation of steroidal molecules," J. Chem. Soc., Perkin Trans. 1, 1998, pages 1139-1142.	

Examiner
Signature

Date
Considered